DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 15, 2015

Osteogenics Biomedical, Inc.
Mr. Shane Shuttlesworth
President
4620 71st St, Bldg 78
Lubbock, Texas 79424

Re: K141177
Trade/Device Name: Vitala® Porcine Derived Collagen Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: August 4, 2015
Received: August 6, 2015

Dear Mr. Shuttlesworth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141177

Device Name

Vitala Porcine Derived Collagen Membrane

Indications for Use *(Describe)*

Vitala Porcine Derived Collagen Membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for:
-Simultaneous use with implants;
-Augmentation around implants placed in immediate extraction sockets;
-Augmentation around implants placed in delayed extraction sockets;
-Localized ridge augmentation for later implantation;
-Alveolar ridge reconstruction for prosthetic treatment;
-Alveolar ridge preservation consequent to tooth extraction;
-Filling of bone defects after root resection, cystectomy, removal of retained teeth;
-Over the window in lateral window sinus elevation procedures;
-Furcation defects in multi-rooted teeth;
-Treatment of recession defects, together with coronally positioned flap;
-In implants with vertical bone loss due to infection, only with satisfactory debridement and implant surface disinfection;
-Guided bone regeneration in dehiscence defects; and
-Guided tissue regeneration in periodontal defects.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92 and to notify the agency of manufacturing changes that resulted in product specification changes.

I. SUBMITTER

Applicant Name:	Osteogenics Biomedical, Inc.
Address:	4620 71st St, Bldg. 78 Lubbock, Texas 79424
Phone:	(806) 796-1923
Fax:	(806) 796-0059
Contact Person:	Shane Shuttlesworth President

Date Prepared:	September 10, 2015

II. DEVICE

Trade Name:	Vitala® Porcine Derived Collagen Membrane
Common Name:	Porcine Derived Collagen Membrane
Regulation Number:	21 CFR 872.3930
Regulation Name:	Bone Grafting Material
Regulatory Class:	II
Product Code:	NPL (Barrier, Animal Source, Intraoral)

III. PREDICATE DEVICE

Predicate Device:	Vitala® Resorbable Natural Collagen Membrane (Osteogenics Biomedical, Inc.) K101453

Bio-Gide® Resorbable Bilayer Membrane (K050466) was used as a reference device in this submission.

IV. DEVICE DESCRIPTION

Vitala® Porcine Derived Collagen Membrane is a natural collagen membrane for use in periodontal and/or dental surgical procedures. The membrane is manufactured using a standardized, controlled, multistage process. The pre-slaughter origin of all animals is the United States of America and the source collagen is extracted from veterinary-certified pigs sacrificed in a USDA-inspected facility. The membrane is terminally sterilized in double blister packs by electron beam irradiation. The contents of the unopened, undamaged inner package are sterile.

Vitala® Porcine Derived Collagen Membrane functions as a barrier when applied between bone graft material and soft tissue. The membrane serves as a bioresorbable scaffold that is eventually remodeled and resorbed and replaced by host tissue. Animal studies have shown that Vitala® Porcine Derived Collagen Membrane is substantially resorbed by 26 weeks.

V. INDICATIONS FOR USE

Vitala® Porcine Derived Collagen Membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for:

- Simultaneous use with implants;
- Augmentation around implants placed in immediate extraction sockets;
- Augmentation around implants placed in delayed extraction sockets;
- Localized ridge augmentation for later implantation;
- Alveolar ridge reconstruction for prosthetic treatment;
- Alveolar ridge preservation consequent to tooth extraction;
- Filling of bone defects after root resection, cystectomy, or removal of retained teeth;
- Over the window in lateral window sinus elevation procedures;
- Furcation defects in multi-rooted teeth;
- Treatment of recession defects, together with a coronally positioned flap;
- In implants with vertical bone loss due to infection, only with satisfactory debridement and implant surface disinfection;
- Guided bone regeneration of dehiscence defects; and
- Guided tissue regeneration in periodontal defects.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Vitala® Porcine Derived Collagen Membrane has been determined to be substantially equivalent to the predicate device having similar technological characteristics as follows:

Parameter	Vitala® Porcine Derived Collagen Membrane (This submission)	Vitala® Resorbable Natural Collagen Membrane (Predicate Device)
Indications for Use	Vitala® is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for: • Simultaneous use with implants; • Augmentation around implants placed in immediate extraction sockets; • Augmentation around	Vitala® is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for: • Simultaneous use with implants; • Augmentation around implants placed in immediate extraction sockets; • Augmentation around

	implants placed in delayed extraction sockets; • Localized ridge augmentation for later implantation; • Alveolar ridge reconstruction for prosthetic treatment; • Alveolar ridge preservation consequent to tooth extraction; • Filling of bone defects after root resection, cystectomy, removal of retained teeth; • Over the window in lateral window sinus elevation procedures; • Furcation defects in multi-rooted teeth; • Treatment of recession defects, together with coronally positioned flap; • In implants with vertical bone loss due to infection, only with satisfactory debridement and implant surface disinfection; • Guided bone regeneration in dehiscence defects; and • Guided tissue regeneration in periodontal defects. Rx Only	implants placed in delayed extraction sockets; • Localized ridge augmentation for later implantation; • Alveolar ridge reconstruction for prosthetic treatment; • Alveolar ridge preservation consequent to tooth extraction; • Filling of bone defects after root resection, cystectomy, removal of retained teeth; • Over the window in lateral window sinus elevation procedures; • Furcation defects in multi-rooted teeth; • Treatment of recession defects, together with coronally positioned flap; • In implants with vertical bone loss due to infection, only with satisfactory debridement and implant surface disinfection; • Guided bone regeneration in dehiscence defects; and • Guided tissue regeneration in periodontal defects. Rx Only
Design	The membrane is manufactured using a standardized, controlled, multistage process. The pre-slaughter origin of all animals is the United States of America and the source collagen is extracted from veterinary-certified pigs sacrificed in a USDA-inspected facility. The membrane is terminally sterilized in double blister packs by electron beam irradiation. The contents of the unopened, undamaged inner package are sterile.	The membrane is manufactured using a standardized, controlled, multistage process. The pre-slaughter origin of all animals is the United States of America and the source collagen is extracted from veterinary-certified pigs sacrificed in a USDA-inspected facility. The membrane is terminally sterilized in double blister packs by electron beam irradiation. The contents of the unopened, undamaged inner package are sterile.
Mode of Action	Vitala® functions as a barrier when applied between bone graft material and soft tissue. The membrane serves as a bioresorbable scaffold that is eventually remodeled and	Vitala® functions as a barrier when applied between bone graft material and soft tissue. The membrane serves as a bioresorbable scaffold that is eventually remodeled and

	resorbed and replaced by host tissue. Animal studies have shown that Vitala® is substantially resorbed by 26 weeks.	resorbed and replaced by host tissue. Animal studies have shown that Vitala® is substantially resorbed by 26 weeks
Operating Principles	Cell-Occlusive Implantable Resorbable Biocompatible	Cell-Occlusive Implantable Resorbable Biocompatible
Material	Intact purified collagen tissue	Intact purified collagen tissue
Collagen Source	Porcine pericardium	Porcine pericardium
Form	Membrane	Membrane
Color	White to off-white	White to off-white
Sizes	Variety of sizes	Variety of sizes
Resorption Time	Substantially resorbed by 26 Weeks	Substantially resorbed by 26 weeks
Sterilization Method	Irradiation	Irradiation
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}
Singe Use/Reuse	Single use only	Single use only
Packaging	Double blister pack	Double blister pack

Additional steps in the manufacturing process of Vitala® Porcine Derived Collagen Membrane were added. Minor differences exist in thickness and tensile strength. Non-clinical performance data was compared against the reference device, Bio-Gide® Resorbable Bilayer Membrane, to substantiate thickness and tensile specifications for the subject device.

VII. PERFORMANCE DATA

Nonclinical Tests Submitted

The substantial equivalence of Vitala® Porcine Derived Collagen Membrane and its predicate was demonstrated based on *in vitro* characterization studies, biocompatibility studies, *in vivo* animal studies, and clinical history of the predicate device.

Non-clinical testing was performed in accordance with FDA recognized consensus standards and FDA guidelines as follows:

ISO 22442-1 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 1 Analysis and Risk Management

ISO 22442-2 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 2 Controls on Sourcing, Collection, and Handling

ISO 22442-3 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents

ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity

ISO 10993-6 Biological Evaluation of Medical Devices – Part 6: Test for local effects after implantation

ISO 10993-18 Biological Evaluation of Medical Devices – Part 18: Chemical characterization of materials

In vitro product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate device. A series of bench tests were conducted to evaluate material properties, biological properties, chemical and physical properties.

Tensile strength was characterized and compared to the reference device, Bio-Gide® Resorbable Bilayer Membrane, in order to establish a minimum acceptable specification.

The comparative bench testing is summarized in the table below.

Test	**Test Method**	**Results**
Tensile Strength	ASTM D1708	Tensile strength ≥ reference device.
Denaturation Transition Temperature	Internal test method using differential scanning calorimetry	Denaturation transition temperature similar to predicate
Protein Analysis	Internal test method using sodium dodecyl sulfate polyacrylamide gel electrophoresis	Protein analysis similar to predicate device.

A series of *in vitro* and *in vivo* biocompatibility testing was performed to assess biocompatibility of the Vitala® Porcine Derived Collagen Membrane as an implantable material.

An animal study was conducted in a rabbit intra-oral model following ISO 10993-6 Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation comparing the subject device, Vitala® Porcine Derived Collagen Membrane, to the reference device, Bio-Gide® Resorbable Bilayer Membrane.

The subject device passed the following FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices.

Test	**Test Method/Model**	**Results**
Cytotoxicity	ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells, ISO 10993-5	Non-cytotoxic.
Implantation	Assessment of Local Tissue Reaction in an Intra-Oral Implant Model in Rabbits, ISO 10993-6	The subject device is considered a non-irritant compared to the reference device at 2, 13, and 26 weeks of implantation.
Pyrogenicity	USP Bacterial Endotoxin Testing,	Non-pyrogenic. The test article

	Kinetic Chromogenic Method	extract met the requirements of the test.
Chemical Characterization	Chemical Characterization of Materials, ISO 10993-18	All compounds have an acceptable margin of exposure.

Additionally, an animal study was conducted in a canine mandibular molar furcation defect model to characterize tissue reaction and resorption.

VIII. CONCLUSION

Additional steps in the manufacturing process of Vitala® Porcine Derived Collagen Membrane were added to the predicate device, resulting in the subject device. Minor differences exist in thickness and tensile strength. Non-clinical performance data was compared against the reference device, Bio-Gide® Resorbable Bilayer Membrane, to substantiate thickness and tensile specifications for the subject device.

The results of *in vitro* device characterization tests show that the subject device, Vitala® Porcine Derived Collagen Membrane, is substantially equivalent to the predicate device. Tensile strength tests show that the subject device is at least as strong as the reference device. Biocompatibility testing demonstrated that the subject device is a non-irritant compared to the reference device. An animal study conducted in a canine mandibular molar furcation defect model characterized resorption.